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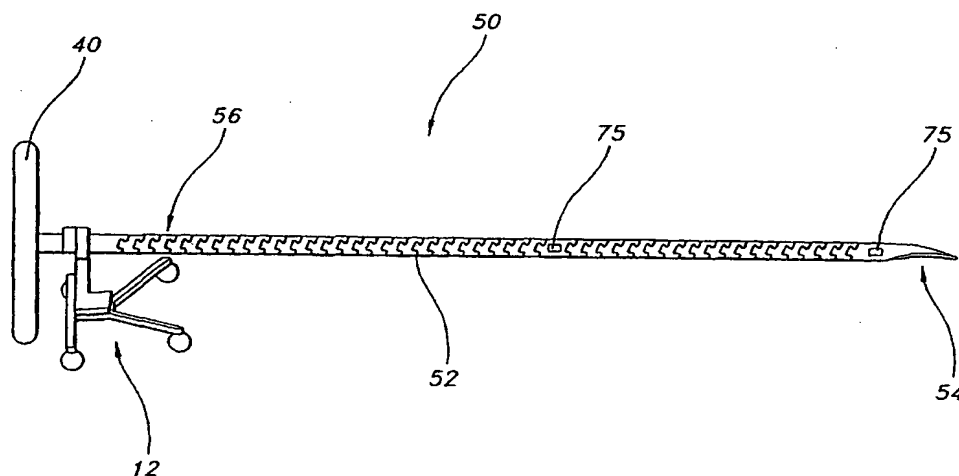
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(54) Title: IMAGE-GUIDED FRACTURE REDUCTION



(57) Abstract: Embodiments of the present invention include products and methods for reducing fractures with the aid of image guidance. In one embodiment, products and methods are directed to reduction for the placement of an intramedullary nail.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

IMAGE-GUIDED FRACTURE REDUCTION

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application No. 60/355,886
5 entitled "Image-Guided Fracture Reduction" filed on February 11, 2002, the contents of
which are incorporated herein by reference.

TECHNICAL FIELD

The invention is directed to treating skeletal fractures. More specifically, products
10 and methods for reducing fractures with the aid of image guidance are disclosed.

BACKGROUND OF THE INVENTION

Fracture fixation of long bones such as the femur, tibia, humerus, fibula, or other long
bones is challenging because of the difficulty of properly aligning and then securing fractured
15 bone segments in place to allow the bone to heal. One very effective means of securing such
fractures is intramedullary nailing. Intramedullary nailing is well-known in the art and
essentially entails aligning two or more segments of bone that result from a fracture about a
rod or nail that fits down the medullary canal of the fractured bone. Various techniques for
intramedullary nailing are discussed in U.S. Pats. Nos. 5,951,561 and 6,010,506, which are
20 hereby incorporated by reference.

Whether fixation is by intramedullary nailing or by some other means, the
repositioning of the segments of a long bone fracture (fracture reduction) is one of the most
challenging aspects of fracture fixation. The contraction of soft tissue subsequent to a
fracture tends to shorten the fractured limb and place the fractured segments of the bone out
25 of alignment relative to each other. Repositioning these segments to restore anatomic
alignment can be very challenging.

One technique for realigning fractured bones comprises the use of a fracture table to
first distract a limb back to its original length. When a patient is positioned and secured on
the fracture table, a surgeon may then manipulate segments laterally to realign the segments.
30 However, fracture tables are expensive and many surgeons do not use them due to cost,
availability, or the limitations of having a patient fixed in one position. Multiple intra-
operative x-ray or fluoroscopic images may need to be taken to assure alignment of the
segments in all planes. Additionally, a fracture may continue to shift out of alignment as
fixation is applied.

Another method for fracture reduction includes the attachment of an external distraction device to the bone via bone pins that pass through soft tissue and attach to the bone. These types of devices allow a surgeon to turn a threaded knob or other actuator and pull a fracture apart. Once distracted, repositioning is then accomplished by manual, physical manipulation of the limb. Once again, multiple intra-operative x-ray or fluoroscopic images may be necessary to assure proper realignment of the segments, and segments may shift out of alignment as fixation is applied.

Another method for fracture repositioning or reduction is through the use of the Internal Fracture Reduction Device manufactured by Smith & Nephew, Inc. This device is inserted into a portion of the fractured long bone and allows manipulation of a segment of the fractured bone. However, such a device must be inserted over a guide rod that has already been placed through the medullary canal of all fractured bone segments. Therefore, placement of the guide rod first requires at least adequate fracture alignment to place the guide rod through the realigned medullary canal.

Smith & Nephew, Inc. also manufactures a reducer for use with its TRIGENTM brand intramedullary nailing system. As shown in Figure 1, the reducer 100 is an elongated, cannulated tube 101 with a connector 102 for attaching a handle 103. The inner diameter of the tube 101 is large enough to accommodate the passage of a guide rod (not shown). The outer diameter of the tube 101 is small enough to be inserted into a long bone without reaming the bone. The tube 101 is typically formed to the same shape as the intramedullary nail that will subsequently be implanted in the bone. The distal tip of the tube 101 includes a finger 104 that is bent up slightly. This finger 104 serves several purposes.

First, the finger 104 can be used to deflect a guide rod as the end of the guide rod passes the end of the tube 101. Specifically, the guide rod may be deflected in a desired direction by rotating the reducer 100 such that the distal end of the finger 104 is pointed in the desired direction. Second, the finger 104 places resistance on a guide rod that passes into or through the finger 104, thereby holding the guide rod in position relative to the reducer 100 by friction. Third, the curved tip of the finger 104 allows the reducer 100 to be pushed smoothly through the medullary canal of a proximal segment and into a distal segment. While the TRIGENTM system reducer has significant advantages, multiple intra-operative x-ray, fluoroscopic, or other such images must still be used to assure proper alignment of the segments in all planes as the reducer 100 is inserted.

Several manufactures currently produce image-guided surgical navigation systems that are used to assist in performing surgical procedures. The TREONTM and iONTM systems

with FLUORONAVTM software manufactured by Medtronic Surgical Navigation Technologies, Inc. are examples of such systems. Systems and methods for accomplishing image-guided surgery are also disclosed in USSN 60/271,818 filed February 27, 2001, entitled Image Guided System for Arthroplasty, which is incorporated herein by reference as
5 are all documents incorporated by reference therein. Further image-guided surgery devices, systems, and methods are disclosed in a provisional application entitled SURGICAL NAVIGATION SYSTEMS AND PROCESSES, Application Serial No. 60/355,899, filed on February 11, 2002, hereby incorporated by this reference.

The Medtronic systems use fluoroscopic imaging to capture anatomical characteristics
10 and infrared cameras that detect certain targets placed in the surgical field to track instruments and anatomy. As used herein, an infrared camera can be any type of sensor or detector that is capable of sensing or detecting light of an infrared wavelength. Any number and orientation of so-called targets, fiducials, frames, markers, indicia, or any other desired location-assisting functionality ("references") can be used as targets to be detected by an
15 imaging system or sensor. Other imaging or data capture systems such as CT, MRI, visual, sonic, digitized modeling, traditional x-ray equipment, or any other effective system or technique which has the capacity to image bone or other desired structures or tissue in the body can be used. Such systems generally include transducer functionality for emitting energy or otherwise performing sensing or location of objects and anatomical structure, a
20 processor, mass memory storage, input/output functionality to control and direct operation of the system, and at least one monitor or other visual output functionality for rendering images that may be constructed by the system, whether or not in combination with images obtained from the transducer in real time.

Such systems typically combine processes and functionality for obtaining, storing,
25 manipulating and rendering images of internal body structure with functionality that senses, stores, manipulates and virtually renders representations of components or objects such as instrumentation, trial components, surgical tools and other objects. The systems can then generate and display representations of the objects in combination with images of the body structure or tissue. Such combination renderings can be created using real time imaging of
30 the body structure or tissue, or the system can obtain appropriate imaging of such structure or tissue and later computer generate and display renderings of it. The Medtronic systems, for instance, require the use of references attached to the anatomy, typically in a rigid fashion, such as to bone structure. The system tracks movement of the reference in three dimensions and then generates images of the bone structure's corresponding motion and location.

The references on the anatomy and the instruments either emit or reflect infrared light that is then detected by an infrared camera. The references may be sensed actively or passively by infrared, visual, sound, magnetic, electromagnetic, x-ray, or any other desired technique. An active reference emits energy, and a passive reference merely reflects energy.

5 In some embodiments, the references have at least three, but usually four, markers that are tracked by an infrared sensor to determine the orientation of the reference and thus the geometry of the instrument, implant component or other object to which the reference is attached. References have been attached to surgical and implant devices such as
10 instrumentation, trial instruments, and the like. For example, references have been attached to probes, instruments for placing acetabular cups and trial implants, drill guides, and cutting blocks.

The Medtronic imaging systems allow references to be detected at the same time the fluoroscopy imaging is occurring. Therefore, the position and orientation of the references may be coordinated with the fluoroscope imaging. Then, after processing position and
15 orientation data, the references may be used to track the position and orientation of anatomical features that were recorded fluoroscopically. Computer-generated images of instrumentation, components, or other structures that are fitted with references may be superimposed on the fluoroscopic images. The instrumentation, trial, implant or other structure or geometry can be displayed as 3-D models, outline models, or bone-implant
20 interface surfaces.

Current systems and techniques do not provide for effective image-guided reduction of fractures. Improved products and methods would include structures and techniques for guiding a reducer through the medullary canals of two or more bone segments that have been created by a fracture of a bone. Improved products and methods would also provide for
25 reduced numbers of x-ray, fluoroscopic, or other images, and would not necessitate pre-operative imaging or surgical procedures prior to the primary procedure. Further, improved products and methods would allow alignment of bone segments to occur using images of at least one of the bone segments in combination with images of one or more implements, instruments, trials, guide wires, nails, reducers and other surgically related items, which are
30 properly positioned and oriented in the images relative to the bone segments. Further, improved products and methods would provide for updated monitoring of bone segment positions, and therefore, rapid alignment of bone segments.

SUMMARY

An embodiment according to certain aspects of the invention is a method of aligning segments of a fractured bone. The method involves attaching references to at least two segments of a fractured bone and to a reducer. The position and orientation of at least two of the references are recorded, and the position and orientation of one or more of the segments of the fractured bone and in some embodiments, the reducer, are recorded. Each of the respective segments or reducer is located relative to a respective reference. The reducer is inserted into a medullary canal of one of the segments, and the reducer is aligned with a representation of another of the segments. The reducer is then inserted into a medullary canal of that segment.

Another embodiment according to certain aspects of the invention is a method of enabling reduction of a fractured bone by virtually representing at least one fractured segment of the bone and virtually representing an instrument for aligning two or more segments. The position and orientation of a first segment of the bone is recorded and that first segment is tracked. The position and orientation of the instrument for aligning the segments is recorded and tracked as well. If alignment has been achieved such that the instrument may be engaged with the first segment and a second segment, an indication is provided to a user through a virtual representation.

Still another embodiment according to certain aspects of the invention is an instrument operable with an image-guided surgical navigation system for aligning fractured segments of a bone. The instrument may include at least an elongated body and a reference coupled to the elongated body for enabling the instrument to be located by the image-guided surgical navigation system. The reference may have a predefined physical relationship with the elongated body such that by observing the position and orientation of the reference relative to at least one of the fractured segments, the position and orientation of the elongated body relative to at least one of the fractured segments can be determined.

Yet another embodiment according to certain aspects of the invention is a system for enabling reduction of a fractured bone. The system is operable to virtually represent at least one fractured segment of the bone and virtually represent an instrument for aligning the at least one fractured segment. The system includes a first reference coupled to the at least one fractured segment, and a second reference coupled to the instrument. This embodiment includes a detector operable to collect position and orientation information regarding the at least one fractured segment and the instrument, and a data processing device operable to store

position and orientation information about the at least one fractured segment and the instrument, and to calculate virtual positions of the at least one fractured segment and the instrument based upon inputs from the detector. An indicator device for notifying a user of the relative positions of the at least one fractured segment and the instrument is also provided.

5 Yet a further embodiment according to certain aspects of the invention includes methods, instruments, and systems as described above, wherein the instrument enabling reduction or alignment of a fractured bone is a flexible reducer. The flexible reducer may be an elongated body with an at least partially flexible portion having one or more location elements associated with the flexible body. The one or more location elements can be
10 provided on the flexible portion in order to assist determining the physical relationship of at least certain parts of the flexible portion with respect to a reference, a bone segment, or the surgical table. The at least partially flexible portion may further be provided with a feature or features that impart at least partial rigidity to the reducer.

According to one embodiment of the present invention there is provided an instrument
15 operable with an image-guided surgical navigation system for aligning fractured segments of a bone comprising: an elongated body; and a reference coupled to the elongated body for enabling the instrument to be located by the image-guided surgical navigation system; characterised in that the reference has a predefined physical relationship with the elongated body such that by observing the position and orientation of the reference relative to one or
20 more of the fractured segments, the position and orientation of the elongated body relative to one or more of the fractured segments can be determined.

According to another embodiment of the present invention there is provided a system for enabling reduction of a fractured bone operable to virtually represent at least one fractured segment of the bone and virtually represent an instrument for aligning the at least one
25 fractured segment comprising: a first reference coupled to the at least one fractured segment; a second reference coupled to the instrument; a detector operable to collect position and orientation information regarding the at least one fractured segment and the instrument; a data processing device operable to store position and orientation information about the at least one fractured segment and the instrument, and to calculate virtual positions of the at
30 least one fractured segment and the instrument based upon inputs from the detector; and an indicator device for notifying a user of the relative positions of the at least one fractured segment and the instrument.

According to still a further embodiment of the present invention, there is provided a method of aligning segments of a fractured bone comprising: inserting a reducer operable to

align segments of a fractured bone into a medullary canal of a second segment of fractured bone; attaching a first reference to a first segment of a fractured bone; recording a position and orientation of the first reference relative to a first datum; recording a position and orientation of the first segment relative to a second datum; locating the first segment relative to the first reference; attaching a reducer reference to the reducer; recording a position and orientation of the reducer reference relative to a third datum; locating the reducer relative to the reducer reference; aligning the reducer with a representation of the first segment; and inserting the reducer into a medullary canal of the first segment, characterised in that the reducer is used to assist aligning the segments of the fractured bone.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a prior art reducer.

Figure 2 is a perspective view of an embodiment of a navigated reducer and a segment of bone with an attached reference according to certain aspects of the invention.

15 Figure 3 is a perspective view of a segment of bone with an attached reference according to certain aspects of the invention, where the segment of bone contains an intramedullary nail.

Figure 4 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention.

20 Figure 5 is a side elevation view of the navigated reducer of Figure 4.

Figure 6 is an elevation view of a bracket according to certain aspects of the invention used in embodiments of the navigated reducer.

Figure 7 is a side elevation view of the bracket of Figure 6.

Figure 8 is a cross-section view taken through the bracket of Figure 7.

25 Figure 9 is an enlarged elevation view of the proximal end of the navigated reducer of Figure 4.

Figure 10 is a side elevation view of the proximal end of Figure 9.

Figure 11 is a cross-section view taken through the proximal end of Figure 10.

30 Figure 12 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention being used to reduce a fractured humerus bone.

Figure 13 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention being used to reduce a subtrochanteric fracture in a femur.

Figure 14 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention with a curved elongated body and an adjustable bracket for supporting a reference.

Figure 15 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention with a straight elongated body and an adjustable bracket for supporting a reference.

Figure 16 is an elevation view of an embodiment of a navigated reducer according to certain aspects of the invention with a straight elongated body and a fixed bracket for supporting a reference.

Figure 17 is a perspective view of an active navigated drill guide and a segment of bone with an attached reference according to certain aspects of the invention.

Figure 18 is an elevational view of various fingers or ends of embodiments of a navigated reducer according to certain aspects of the invention.

Figure 19 is a perspective view of a segment of bone with an attached reference according to certain aspects of the invention.

Figure 20 is a perspective view of a segment of bone with an attached reference according to certain aspects of the invention, where the segment of bone contains an intramedullary nail.

Figure 21 is a plan view of an at least partially flexible reducer according to certain aspects of the invention with location elements positioned on the elongated body.

DETAILED DESCRIPTION

Figure 2 shows an instrument 10 according to certain aspects of the invention operable with an image-guided surgical navigation system. As described above, an image-guided surgical navigation system can be any of a variety of systems that capture anatomical characteristics and/or other references connected to the body and/or other surgical devices and/or other structures associated with a reference. Such a system then tracks parts of the body and the surgical devices relative to one another. Generally, reference to a system as "image-guided" means that the system produces images by which surgical navigation information is conveyed to the user. For example, a computer display showing virtual representations of an instrument and its relationship with a bone is considered one example of an image-guided system. As shown in Figure 2, the position and orientation of instrument 10 are being recorded by placing finger 14 on a portion of a bone reference 15. As shown, the bone reference 15 is connected to an upper proportion 16 of a femur. The instrument 10 may

be used to align fractured segments of a bone such as the upper portion 16 of a femur and a lower portion 20 of the femur shown in Figure 3.

As illustrated in Figure 2, instrument 10 includes an elongated body 11 and a reference 12 that is coupled to the elongated body 11. Figure 4 shows elongated body 11 in one embodiment of the invention. As shown, the elongated body 11 is tubular or in similar terminology, cannulated. In other embodiments, the elongated body 11 may be solid. Figures 2 and 12 illustrate an elongated body 11 greater than half the greatest length of the fractured bone 25. In other embodiments such as shown in Figure 13, the elongated body 11 may be less than or equal to half the greatest length of the fractured femoral bone 26. The condition of being less than or equal to half the greatest length is not limited to association with the femur, but can be with regard to any bone. The elongated body 11 may be curved as shown in Figure 14 or substantially straight as shown in Figures 15 and 16. The elongated body 11 shown in Figures 2 and 4 has substantially the same curvature as an implant 21 (for example, the implant shown in Figure 3). Implant 21 may be used to fix bone segments such as upper portion 16 and lower portion 20 in place. The intramedullary reduction device may be bent to follow the shape of whatever implant is used for fixation: IM nails, IM rods, IM hip screws, etc. This has the benefit of positioning the segments in the same position as the subsequent fixation device. However, less exact bends in the elongated body 11 may also be beneficial.

The reference 12 enables the instrument 10 to be located by an image-guided surgical navigation system. As illustrated in Figure 2, reference 12 is coupled to the elongated body 11 in a predefined physical relationship. Figures 4-11 show one embodiment of a structure for coupling the reference 12 to the elongated body 11. As illustrated, a bracket 30 is rigidly affixed near a proximal end 17 of the elongated body 11. As best seen in Figures 6-8, a dovetail mount 31 is located at one end of the bracket 30. The dovetail mount 31 is designed to be received by a reference 12 that has a mating dovetail opening (not shown).

Bracket 30 is shown as adapted to slide over proximal end 17 of elongated body 11. Although not shown, it is understood that the bracket may alternatively be a clamp that opens and closes to secure elongated body 11 or any other attachment device or structure suitable for attaching components to each other. Those skilled in the art will understand that any member that can rigidly attach reference 12 to instrument 10 is considered a "bracket" within the scope of this invention.

Another embodiment of this invention provides a reference 12 having an integral attachment structure (not shown). Attachment structure may be a bracket integrally formed

with reference 12 or any other connection element that will achieve securement of reference 12 to instrument 10.

Figures 14 and 15 show articulating brackets 32 releasably movably coupled with elongated body 11. With such a feature, the instrument 10 can be effectively used on either side of the patient by moving the articulating bracket 32 among two or more predetermined positions. In some embodiments, the instrument 10 is releasably movable between positions located at ninety degree intervals around the elongated body. In other words, viewing elongated body from one end, instrument 10 may be positioned at a first ninety degree position, a second ninety degree position, a third ninety degree position, or a fourth ninety degree position.

It is advantageous in some embodiments of the invention to limit the number of positions to which the articulating bracket 32, and thereby the reference 12, may be positioned. This is because a predefined physical relationship must be maintained between the elongated body 11 and the reference 12. By limiting the number of positions, the number of predefined relationships may be more easily defined and tracked.

Figure 5 illustrates an embodiment of the bracket 30A that is asymmetrically coupled to the elongated body 11. Consequently, if a reference 12 were coupled to the bracket 30A, the reference 12 would also be asymmetrically fixed relative to the elongated body 11. Such an arrangement may be beneficial to more effective use on a particular side of a patient and is sometimes preferred. In other instances, a reference may be symmetrically coupled to the elongated body 11. Preferences are typically dictated by the ability of the image-guided surgical navigation system to effectively detect a reference in a particular application. In some embodiments, the system's detector is a line-of-site device.

The reference 12 may also include energy-reflecting surfaces 13 that are detectable by a sensor. Figure 2 shows four such energy-reflecting surfaces 13 mounted on the reference 12. As illustrated, the energy-reflecting surfaces 13 reflect energy in at least the visible and infrared ranges. However, as discussed in the background section above, various types of energy detectors may be employed. Energy-reflecting surface 13 is considered a passive device because it does not internally generate or convert energy to emit. Figure 17 illustrates an active energy emitting component 23 that is incorporated into an active reference 22. Note that the active reference 22 includes a wire 24 through which electricity is supplied to the active energy emitting components 23. As shown, there are four active energy emitting components 23. As with the passive device, the active energy emitting components 23 may be operable with various types of energy detectors.

In some embodiments of the invention, the instrument 10 may include a handle 40 (shown in Figures 12, 13, 21) connected at proximal end 17. Such a handle 40 would be useful in manipulating the instrument 10 during a surgical procedure. The handle 30 may or may not be removable from instrument 10. If handle 40 is not removable, bracket 30 may be a clamp or other device or structure suitable for attaching components to each other.

Some embodiments of the invention also include a finger 14, shown for example in Figure 4. Figure 18 shows a variety of finger shapes that may also be advantageous in various embodiments of the invention, although different finger shapes may be preferred for various procedures. Note that each of these shapes may be placed on the end of a solid or cannulated elongated body and may themselves be solid or cannulated.

The invention may also be embodied in a system for enabling reduction of a fractured bone. The system is operable to virtually represent at least one fractured segment of the bone and virtually represent an instrument for aligning the at least one fractured segment. The system includes a first reference coupled to the at least one fractured segment, and a second reference coupled to the instrument. The first reference may be coupled to a bone segment through which the instrument is inserted. In this case, position and orientation of another segment of the bone would have to be determined as well, which could be accomplished in any technically effective way.

Alternatively, the first segment could be coupled to a segment of bone toward which the instrument was being directed. In any case, the system also includes a detector operable to collect position and orientation information regarding the at least one fractured segment and the instrument. As discussed in the background section above, the detector could be an infrared camera, visual camera, or any of a variety of sensors capable of detecting any kind of reference or characteristic. The system also includes a data processing device operable to store position and orientation information about one or more fractured segments and the instrument. The data processing device calculates virtual positions of the at least one fractured segment and the instrument based upon inputs from the detector. Such calculations could involve matrix transformations, table look-up functionality, or any other operation effective in calculating the respective virtual positions. An indicator device for notifying a user of the relative positions of the at least one fractured segment and the instrument is also provided. Such an indicator could be a visual cue on a computer screen such as color changes or alignment of articulating lines, sounds, flashes of light, or any device for showing a changeable condition, or some combination of any of these.

Another embodiment of the invention is a method of aligning segments of a fractured bone. As shown in Figure 3, one method includes attaching a first reference, such as a distal reference 18, to a first segment of a fractured bone, such as a lower portion 20. The position and orientation of distal reference 18 may then be recorded relative to a first datum. As used
5 herein, the term "recording" includes without limitation capturing or storing in computer memory or on a tangible medium such as film. Any such acquisition of information associated with position or orientation, regardless of how transiently maintained in a system, medium, or component is within the definition of recording as used herein. In some
10 embodiments of the invention, recording may include the use of an infrared camera that registers the positions of energy-reflecting surfaces 13.

Alternatively, a reference may not be coupled with a segment of bone, but may be attached to a probe. Such a probe may be recorded at a predetermined anatomical position and orientation. Therefore, by knowing the position of the reference attached to the probe, and the probe's position and orientation on the anatomy, the position of the anatomy can be
15 calculated. In either case, a position and orientation of the first segment of the bone relative to a second datum is recorded. Such a recording may be accomplished by capturing fluoroscopic images of the first segment. As discussed in the background section, the imaging may be through processes other than fluoroscopic imaging, such as CT, MRI, or other effective technologies. The first datum may be the same as the second datum, or
20 information relating the first datum and the second datum may be stored such that transforms relating their relative positions may be calculated. As a result, the first segment will be located relative to the first reference.

The term "datum" as used herein is generally a coordinate system to which three-dimensional association can be made. As such, a number of datums can be defined and then
25 associated to one another by use of three-dimensional transforms, matrix calculations, or the like. Such calculations are well-suited to implementation on computing devices. Similarly, objects being tracked can be positioned and oriented relative to a single datum. In any case, to effectively track objects' positions and orientations, association among the objects must be established and maintained. A strength of the current system is that sensor or camera
30 positions and orientations and patient and instrument positions and orientations may change relative to one another, but through the tracking that embodiments of the invention provide, accurate location and bone segment alignment can be accomplished.

As shown in Figure 2, a second reference, such as bone reference 15, may be attached to a second segment, such as upper portion 16. As with the first segment and reference, the

positions and orientations of the second reference and the second segment are recorded relative to respective third and fourth datums, and the second segment is located relative to the second reference.

5 A third reference is attached to an instrument 10, such as a reducer. As described above, the reducer is operable to align segments of a fractured bone through the medullary canal of the segments. The term "reducer" as used herein may refer more generally to any instrument used to assist with the alignment of bones. As with the first and second references, a position and orientation of the third reference relative to a fifth datum is recorded. In the case of a reducer or other instrument, locating the reducer relative to the
10 third reference is simplified because there is a predetermined relationship between the reducer and the third reference. As discussed in association with the bracket 30, a single or at least finite number of predetermined relationships between portions of the instrument and the associated reference may be defined. Given a predetermined setting of the instrument relative to the reference, tracking of the reference is effective to track the instrument.
15 Recording of the third reference position and orientation may be accomplished inter-operatively or prior to the beginning of an operation.

Once all of the references, segments, and instrument (or instruments) have been located, they may all be continuously or intermittently tracked without the use of fluoroscopy for as long as desired. As used herein, "continuously" shall mean at a rate that appears
20 substantially continuous to a user, but could include tracking accomplished at a standard electronic sampling rate such as a rate greater than one sample per second. Typically, this tracking is accomplished by use of a computer system that is interfaced with an infrared camera or other device, the computer also calculating transforms regarding each datum and its relationship to each other datum.

25 Insertion of the instrument 10 may be accomplished prior to, during, or after the process of recording and locating described above. With each of the first segment, the second segment, and the reducer being tracked, the reducer can be aligned with a representation of the second segment. For instance, a surgeon could hold and manipulate a first segment of fractured bone with an inserted reducer while observing a representation of
30 the second segment on a computer screen. The image on the computer screen may also include representations of other bone segments or instruments, such as the reducer. When an indication is received that alignment has been achieved, the surgeon inserts the reducer into the medullary canal of the second segment. The upper portion 16 of a femur shown in Figure

2 and the lower portion 20 of a femur shown in Figure 3 are merely examples of the first and second segments.

As previously discussed, the fractured bone need not be a femur. Additionally, the first and second segments may be either the lower or upper portions of bone, depending upon surgeon preference. In many orthopedic procedures, entry can be made from two or more possible approaches.

In some embodiments of the invention, a representation of alignment may include only a representation that the first segment and the second segment, each of which is being tracked, are aligned. In other embodiments, the key to a representation of alignment may be the reducer that is being tracked.

In some embodiments of the invention, only two of a first segment, a second segment, and an instrument may need to be recorded, located, and tracked. For example, if two segments are being tracked, alignment of those segments could be indicated to the user. Given the fact that the user knows that the reducer is located in the medullary canal of one of the segments, the user would know that the reducer could be pushed into the medullary canal of the other segment. Similarly, if only the reducer and the segment into which the reducer is to be inserted second are being tracked, the locations of only that second segment and the reducer could be represented to the user. In this embodiment, the reducer is located in the medullary canal of the other segment. Therefore, by aligning the reducer with the segment into which the reducer is to be inserted second, the user has adequate information to accurately complete the procedure.

In other embodiments and for some procedures, an at least partially flexible reducer 50, as shown in Figure 21, may be beneficial. For instance, a surgeon may desire to use a flexible reducer if the bone fracture to be aligned or reduced is so misaligned that a rigid reducer is not workable or would be particularly difficult to use. For example, two bone segments of a fracture may be so offset from one another that a rigid reducer would not appropriately engage the second segment. In these instances, the at least partially flexible reducer 50 of the present invention could be used. (For the purposes of this document, "at least partially flexible" and "flexible" mean capable of being even slightly flexed or bent, turned, bowed, or twisted, without breaking; or pliable; or yielding to pressure, whether strong pressure or slight pressure.) The flexible reducer 50 is at least partially flexible to allow the surgeon to more easily manipulate the flexible reducer 50 in order to properly guide it into the second segment. It should be understood that there may be other instances in which a flexible reduced 50 may be preferred.

Flexible reducer 50 according to the particular embodiment shown in Figure 21 features an at least partially flexible elongated portion or shaft 52. The at least partial flexibility may be provided by a shaft that is hollow, cannulated, or solid. The shaft may have a spiral or helical configuration, a laser cut shaft, a shaft of a material that becomes
5 flexible when subjected to heat (for example, nitinol), a shaft of a thin material that permits flexibility, a shaft with a plurality of flexible elements joined by a connection, a shaft having a series of inter-engaged links, a shaft with a plurality of slots (provided in any configuration) cut at an angle relative to the shaft, a plastic tube (or any other material that provides at least partial elasticity), or any other design that provides a reducer of a flexible nature. Examples
10 of flexible shafts are provided in U.S. Patent 6,053,922, which is incorporated herein by this reference.

Once flexible reducer 50 has been positioned with respect to both bone segments, the surgeon may wish to impart at least partial rigidity to the flexible reducer 50 in order to more properly align the bone segments. In this instance, flexible reducer 50 can be provided with a
15 separate rigid member (not shown), a feature or features on the flexible reducer 50 itself that imparts rigidity to the flexible reducer (also not shown), or any structure or mechanism that imparts at least partial rigidity to reducer 50.

For example, the flexible reducer 50 may be provided with a rigid member with an outer diameter smaller than the inner diameter of the flexible reducer 50, such that inserting
20 the rigid member through the flexible reducer adds rigidity at the desired point in the procedure. Alternatively, the flexible reducer 50 itself can be provided with a cable or wire disposed through the flexible reducer 50 such that when the cable or wire is pulled taut, the flexible shaft 52 is forced to undertake at least partial rigidity. Flexible reducer 50 may alternatively be provided with a trigger, such that once the trigger is activated, the flexible
25 portions become rigid. The flexible portions may be made rigid by a magnetic force, by a mechanical force, or any other mechanism that imparts at least partial rigidity to the flexible reducer 50 at a specified time during the surgery. It should be understood that any feature that provides an at least partially flexible reducer 50 with at least partial rigidity is considered a feature that imparts at least partial rigidity to the reducer within the scope of this invention.

30 One challenge presented with the use of a flexible reducer 50 is the fact that, by its very nature, it is flexible, and thus, does not retain a rigid position from tip 54 to end 56 in relation to reference 12. This presents a challenge to the use of the image-guided systems and methods described herein, because the flexible elongated portion 52 will not necessarily remain in a fixed position with respect to the reference 12 (or any other reference point being

used, such as a bone segment, another instrument, a surgical table, etc.) in order to provide the surgeon with accurate cues about its physical position. Thus, there is also a need to provide a way to determine the position of the flexible elongated portion 52 when it is flexed in a particular direction.

5 Flexible reducer 50 is consequently provided with one or more location elements 75. One or more location elements 75 assist the determination of at least portions of the physical relationship of the flexible elongated portion 52 with respect to reference 12. A location element 75 may be provided at or near the tip 54 of flexible elongated portion 52, at or near the middle of flexible elongated portion 52, at multiple positions along the flexible elongated
10 portion 52, or any combination of these positions. The location elements may be spaced as close together or as far apart as necessary. The more location elements 75 provided, the more trackability is provided to flexible elongated portion 52.

 Location element 75 may be any component or device that permits the physical position of flexible elongated portion 52 to be sensed, detected, imaged, or mapped with
15 respect to reference 12. For example, location elements 75 may be sensed actively or passively by one or more of the following methods: infrared, visual, reflective, sound, ultrasound, radio waves, mechanical waves, magnetic, electromagnetic, electrical, x-ray, GPS systems or chips, transponder, transducer, or any other desired technique. This list is not intended to be inclusive, and any way in which the location of flexible elongated portion 52
20 can be relayed to a component that can track, sense, image, or map flexible elongated portion 52 for the surgeon to view is considered within the scope of this invention. It should be understood, however, that the flexible elongated portion 52 will be positioned within patient tissue in use, so the location method chosen should be able to sense location element 75 through various tissues, such as bone, muscle, blood, and skin.

25 Location elements 75 are preferably configured to sense, track, image, and map the physical position of reducer 50 in any plane, location, and/or orientation. In other words, in addition to sensing and tracking the medial-to-lateral movement of flexible reducer 50, location elements 75 are also preferably adapted to sense and track anterior-to-posterior movement.

30 Location elements may be provided in any configuration or any shape. It is possible for location elements 75 to sense 2-dimensional movement for a rough view of the reducer's location and orientation. In other aspects of the invention, the location elements 75 sense 3-dimensional movement and provide a finer ability to sense and track the location and orientation of reducer 50. Location elements 75 may be provided in any shape or

configuration, such as the square-like elements 75 shown in Figure 21, oval or round-like elements, cross-shaped elements, band-shaped elements, indented elements, bead-shaped elements, and so forth.

Location elements may be located along only one side of flexible elongated portion 52, wrapped around elongated portion 52, positioned in specific increments from one another, or scattered in various, unequal positions about elongated portion 52. As previously mentioned, embodiments according to various aspects of this invention may include only a single location element 75.

A single location element 75 may be used to track and sense the location and orientation of elongated portion 52 with respect to reference 12. To the extent that any other reference point is being used, such as another instrument, a bone segment, or another reference point, it is preferred that two or more location elements 75 be provided.

Location elements 75 may operate in conjunction with systems which are preferably connected to other systems according to various aspects of the invention which sense and track references 12, body portions, instruments, components of other devices, and so forth.

Embodiments of the invention are directed toward enabling reduction of a fractured bone by virtually representing at least one fractured segment of the bone and virtually representing an instrument for aligning two or more segments of bone. As described above, positions and orientations of a segment of bone and an instrument may be recorded and tracked in three-dimensional space with the use of cameras or sensors, imaging devices, and a digital computer. Then, through the use of a sound, visualization, or other stimulation, an indication that alignment has been achieved is provided to a user. Alternatively or in addition, indications regarding the progress of alignment may be provided to the user. "Tracking" as defined for use in this embodiment can include both detecting distinguishing characteristics, such as references or instrument configurations, and processing information regarding changes in position and orientation.

Therefore, embodiments of the invention provide for the location and tracking of bone segments and instruments such that the instruments may be aligned to assist with fixation or therapy. This is accomplished with reduced numbers of x-ray, fluoroscopic, and other such energy-intense imaging devices. There is no requirement for pre-operative imaging or any surgical procedures prior to the primary procedure. With various embodiments of the invention, continuous or nearly continuous monitoring of bone segment and instrument positions is accomplished. Therefore, rapid alignment of bone segments and instruments is facilitated using images of at least one of the bone segments in combination with images

of one or more implements, instruments, trials, guide wires, nails, reducers, other surgically related items, or other bone segments which are properly positioned and oriented in the images.

WHAT IS CLAIMED IS:

1. An instrument operable with an image-guided surgical navigation system for aligning fractured segments of a bone comprising:
an elongated body; and
5 a reference coupled to the elongated body for enabling the instrument to be located by the image-guided surgical navigation system;
characterised in that the reference has a predefined physical relationship with the elongated body such that by observing the position and orientation of the reference relative to one or more of the fractured segments, the position and orientation of the elongated body relative to
10 one or more of the fractured segments can be determined.
2. An instrument according to claim 1, characterised in that the elongated body is characterised by having at least one of the following features: tubular, solid, greater than half the greatest length of the fractured bone, less than or equal to half the greatest length of the
15 fractured bone, substantially straight, curved, and substantially the same curvature as an implant to be used to fix the bone segments in place.
3. An instrument according to either of claims 1 or 2, characterised in that the reference comprises an energy-reflecting surface characterised in that the reflected energy is detected
20 by a sensor.
4. An instrument according to either of claims 1 or 2, characterised in that the reference comprises an energy-emitting component that characterised in that the energy is detected by a
25 sensor.
5. An instrument according to any one of claims 1-4, characterised in that the reference is removably coupled to the elongated body.
6. An instrument according to any one of claims 1-5, characterised in that the reference
30 is symmetrically coupled to the elongated body such that the instrument can be effectively used on either side of a patient.

7. An instrument according to any one of claims 1-5, characterised in that the reference is symmetrically coupled to the elongated body such that the instrument is more effectively useable on one side of a patient.
- 5 8. An instrument according to any one of claims 1-7, characterised in that the reference is releasably movable relative to the elongated body such that the instrument can be effectively used on either side of a patient by moving the reference among two or more predetermined positions.
- 10 9. An instrument according to any one of claims 1-8, characterised in that the reference is releasably movable between positions located at ninety degree intervals around the elongated body
10. An instrument according to any one of claims 1-9, further comprising a handle
15 coupled to one end of the elongated body.
11. An instrument according to any one of claims 1-10, further comprising a curved tip.
12. An instrument according to any one of claims 1-11, characterised in that the elongated
20 body is at least partially flexible.
13. An instrument according to any claim 12, characterised in that the at least partially flexible elongated body comprises one or more location elements that can be sensed in location actively or passively.
- 25 14. An instrument according to claim 13, characterised in that the one or more location elements can be sensed in location using one or more of the following techniques: infrared, visual, reflective, sound, ultrasound, radio wave, mechanical wave, magnetic, electromagnetic, electrical, x-ray, GPS systems or chips, transponder, or transducer.
- 30 15. An instrument according to any one of claims 12-14, characterised in that the at least partially flexible elongated body comprises a feature that imparts at least partial rigidity to the reducer.

16. A system for enabling reduction of a fractured bone operable to virtually represent at least one fractured segment of the bone and virtually represent an instrument for aligning the at least one fractured segment comprising:
- a first reference coupled to the at least one fractured segment;
 - 5 a second reference coupled to the instrument;
 - a detector operable to collect position and orientation information regarding the at least one fractured segment and the instrument;
 - a data processing device operable to store position and orientation information about the at least one fractured segment and the instrument, and to calculate virtual positions of the at
 - 10 least one fractured segment and the instrument based upon inputs from the detector; and
 - an indicator device for notifying a user of the relative positions of the at least one fractured segment and the instrument.
17. A method of aligning segments of a fractured bone comprising:
- 15 inserting a reducer operable to align segments of a fractured bone into a medullary canal of a second segment of fractured bone;
 - attaching a first reference to a first segment of a fractured bone;
 - recording a position and orientation of the first reference relative to a first datum;
 - recording a position and orientation of the first segment relative to a second datum;
 - 20 locating the first segment relative to the first reference;
 - attaching a reducer reference to the reducer;
 - recording a position and orientation of the reducer reference relative to a third datum;
 - locating the reducer relative to the reducer reference;
 - aligning the reducer with a representation of the first segment; and
 - 25 inserting the reducer into a medullary canal of the first segment,
 - characterised in that the reducer is used to assist aligning the segments of the fractured bone.
18. A method according to claim 17, further comprising
- attaching a second reference to the second segment of a fractured bone;
 - 30 recording a position and orientation of the second reference relative to a fourth datum;
 - recording a position and orientation of the second segment relative to a fifth datum;
 - locating the second segment relative to the second reference.

19. A method according to any one of claims 17-18, characterised in that the recording a position and orientation of the references or the segments viewing the references or the segments with an infrared camera.
- 5 20. A method according to any one of claims 17-19, characterised in that the recording a position and orientation of the first segment or the second segment comprises capturing a fluoroscopic image of the first segment or the second segment
- 10 21. A method according to any one of claims 17-20, characterised in that the locating the first segment relative to the first reference comprises continuously tracking the first reference until the reducer is aligned.
- 15 22. A method according to any one of claims 17-21, characterised in that the locating the second segment relative to the second reference comprises continuously tracking the second reference until the reducer is aligned.
- 20 23. A method according to any one of claims 17-22, characterised in that the first datum, second datum, third datum, fourth datum, and fifth datum are a common datum.
24. A method according to any one of claims 17-22, characterised in that the first datum, second datum, third datum, fourth datum, and fifth datum are related to one another by calculable transforms.
- 25 25. A method according to any one of claims 17-24, characterised in that the aligning the reducer with a representation of the first segment comprises aligning the first segment relative to the second segment, characterised in that the reducer is inserted in the second segment.
- 30 26. A method according to any one of claims 17-24, characterised in that the aligning the reducer with a representation of the first segment comprises aligning the reducer relative to the first segment.

27. A method according to any one of claims 17-26, characterised in that the attaching a reducer reference to a reducer comprises attaching a reducer reference to an at least partially flexible reducer.
- 5 28. A method according to any one of claims 17-26, characterised in that the attaching a reducer reference to a reducer comprises
attaching the reducer reference to at least partially flexible reducer that comprises one or more location elements;
recording a position and orientation of the one or more location elements relative to the
10 reducer reference attached to the at least partially flexible reducer;
locating the one or more location elements relative to the reducer reference; and
establishing the orientation of the one or more location elements.
29. A method according to either of claims 27 or 28, further comprising:
15 applying a force to the at least partially flexible reducer in order to impart at least partial rigidity to the reducer.
30. A method of enabling reduction of a fractured bone by virtually representing at least one fractured segment of the bone and virtually representing an instrument for aligning two
20 or more segments comprising:
recording a position and orientation of a first segment of the bone;
tracking the position and orientation of the first segment;
recording a position and orientation of the instrument for aligning the segments;
tracking the position and orientation of the instrument; and
25 indicating through a virtual representation to a user that alignment has been achieved such that the instrument may be engaged with the first segment and a second segment.
31. A method according to claims 30, characterised in that the recording a position and orientation of the first segment, the second segment, or the instrument comprises storing data
30 in a computer, the data numerically representing a three-dimensional position and orientation of the first segment, the second segment, or the instrument.

32. A method according to any one of claims 30-31, characterised in that the tracking the first segment or the second segment comprises calculating changes to the data responsive to changes in the position and orientation of the first segment or the second segment.
- 5 33. A method according to any one of claims 30-32, characterised in that the indicating that alignment has been achieved comprises indicating that at least two of the first segment, the second segment, and the instrument are aligned.
34. A method according to any one of claims 30-33, further comprising:
10 recording a position and orientation of a second segment of the bone; and tracking the position and orientation of the second segment.
35. A method according to any one of claims 30-34, characterised in that the recording a position of recording a position and orientation of the first segment relative to a second datum
15 further comprises detecting at least a portion of the second segment through the skin of a patient.
36. A method according to any one of claims 30-35, characterised in that the aligning the reducer with a representation of the first segment further comprises generating an image that
20 comprises a representation of the first segment and a representation of the reducer.
37. A method according to any one of claims 30-36, characterised in that the recording a position and orientation of the instrument for aligning the segments and the tracking the position and orientation of the instrument comprise recording and tracking an at least
25 partially flexible reducer.
38. A method according to any one of claims 30-36, characterised in that the recording a position and orientation of the instrument for aligning the segments and the tracking the position and orientation of the instrument comprise
30 recording and tracking an at least partially flexible reducer that comprises one or more location elements;
recording a position and orientation of the one or more location elements;
tracking the position and orientation of the one or more location elements; and
establishing the orientation of the one or more location elements.

39. A method according to either of claims 37 or 38, further comprising:
applying a force to the at least partially flexible reducer in order to impart at least partial rigidity to the reducer.

5

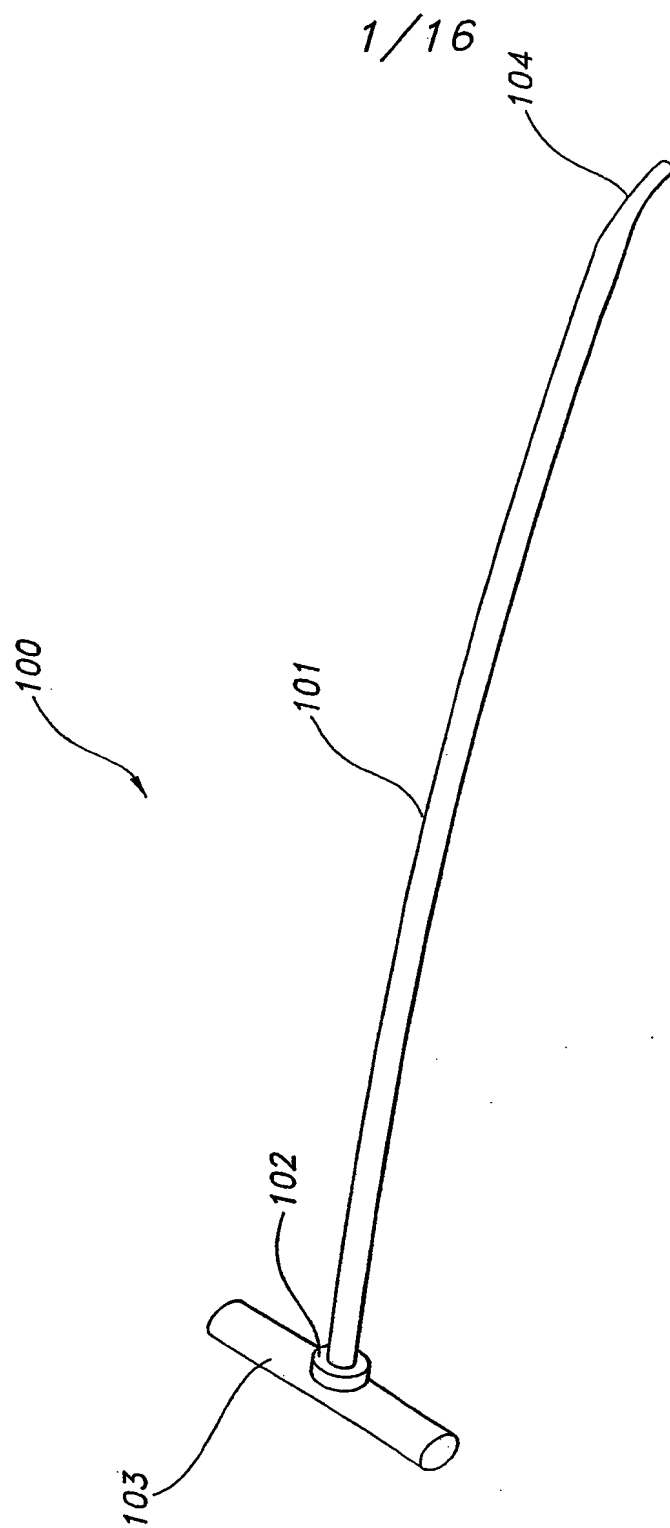


FIG. 1
(PRIOR ART)

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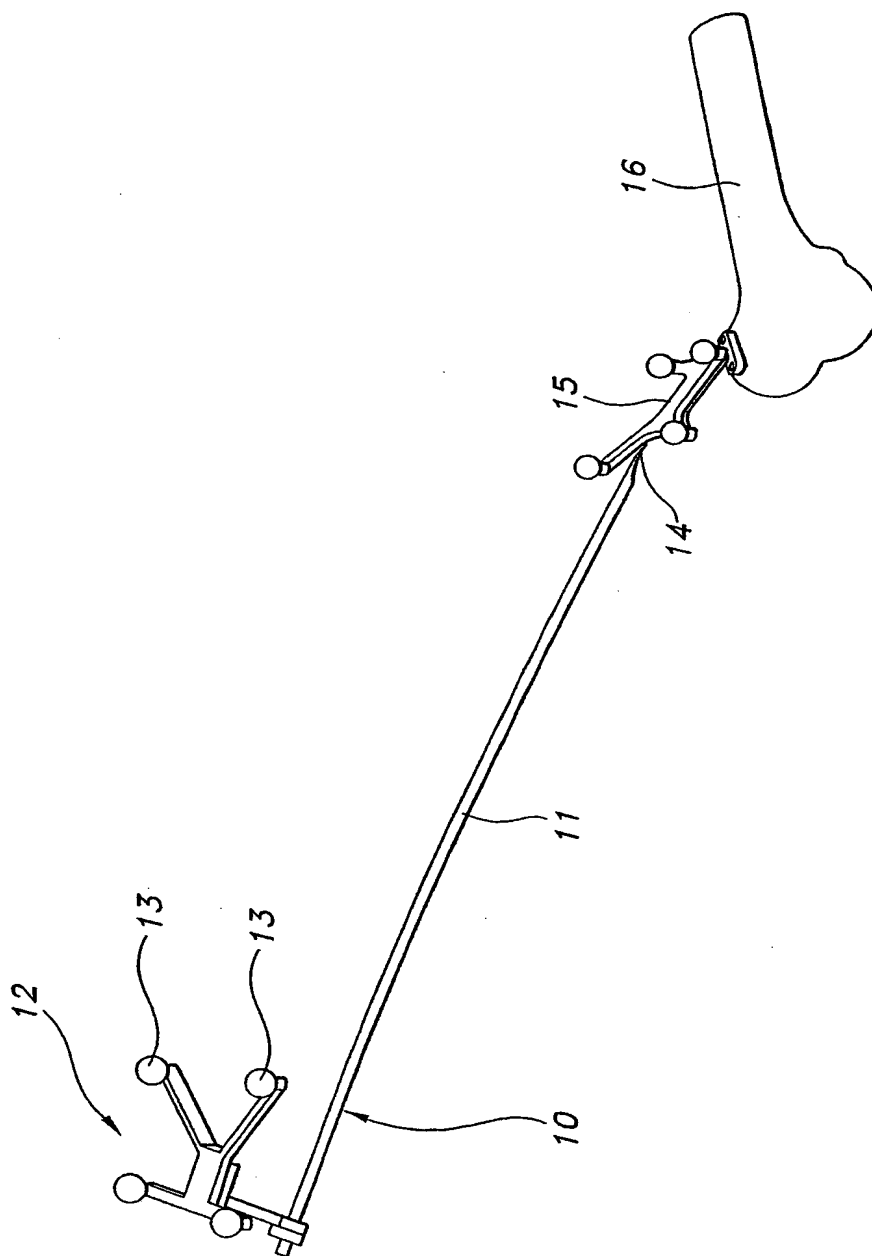


FIG. 2

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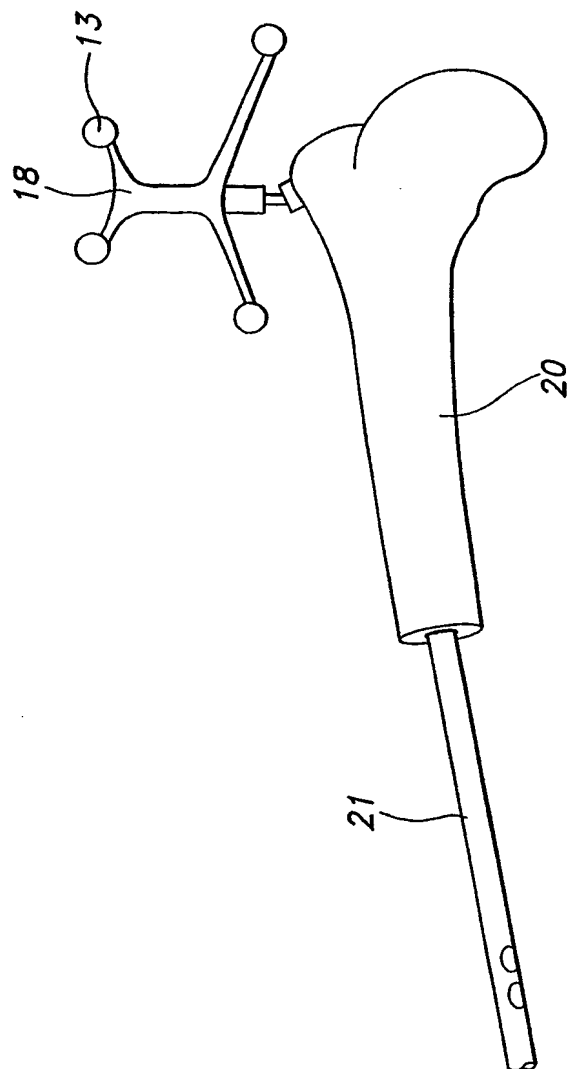


FIG. 3

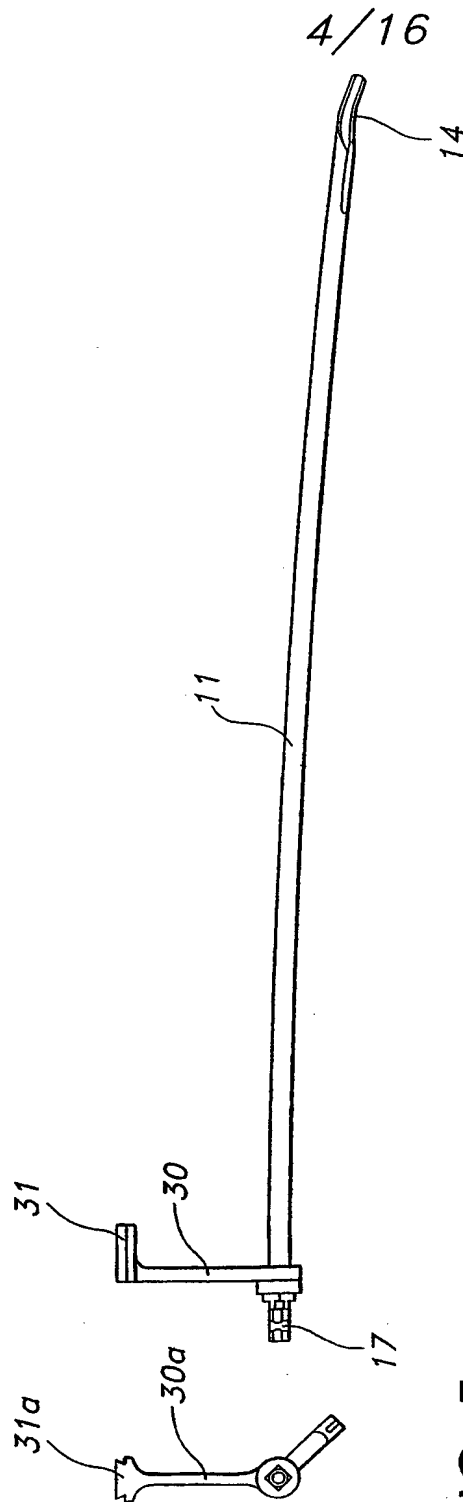


FIG. 4

FIG. 5

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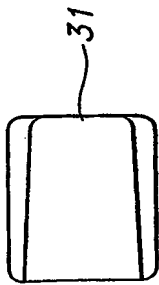


FIG. 22

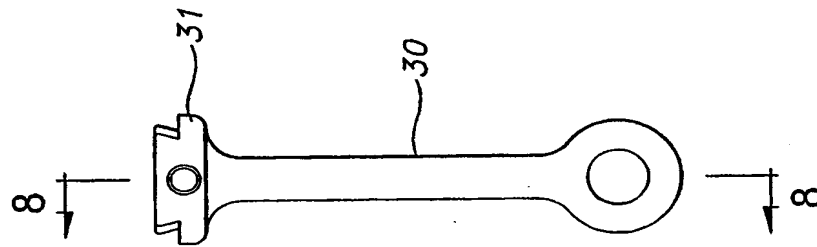


FIG. 7

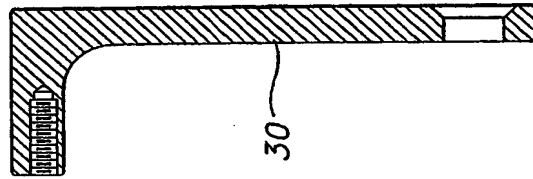


FIG. 8

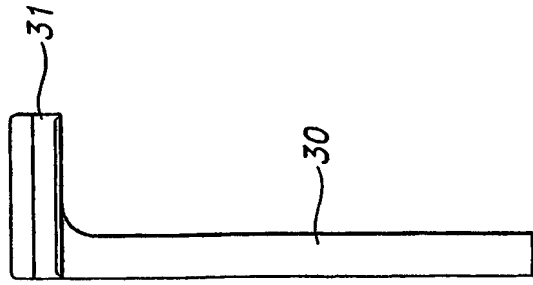


FIG. 6

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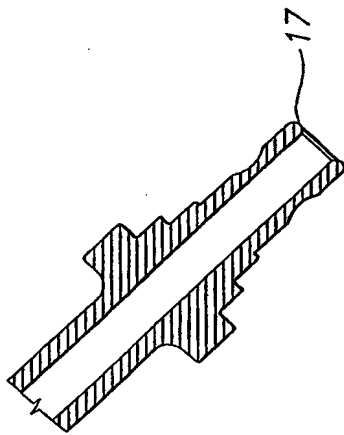


FIG. 11

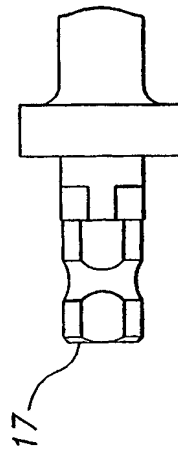


FIG. 9

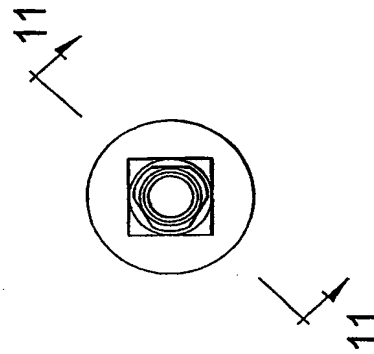


FIG. 10

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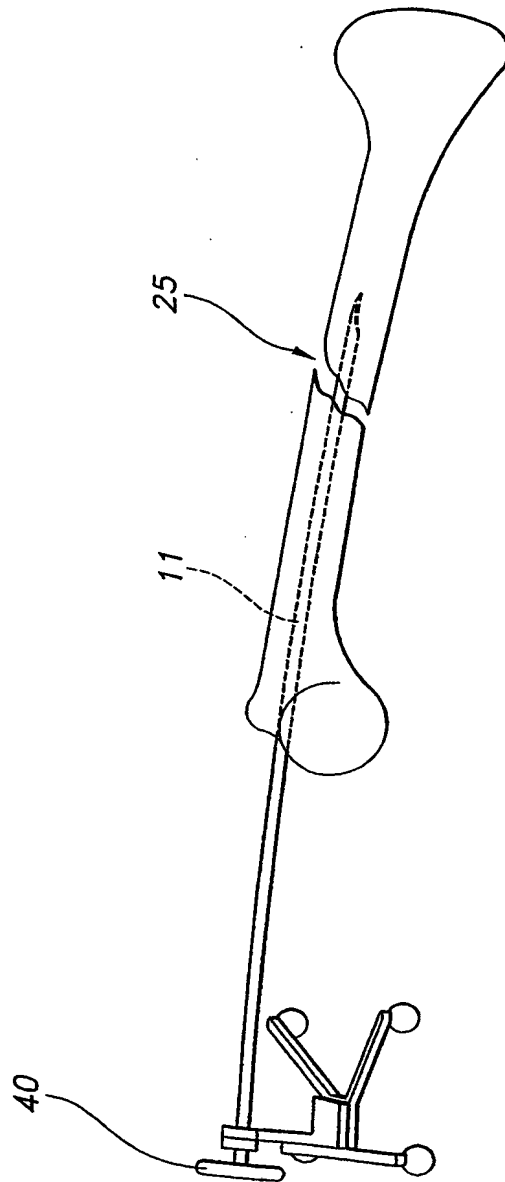


FIG. 12

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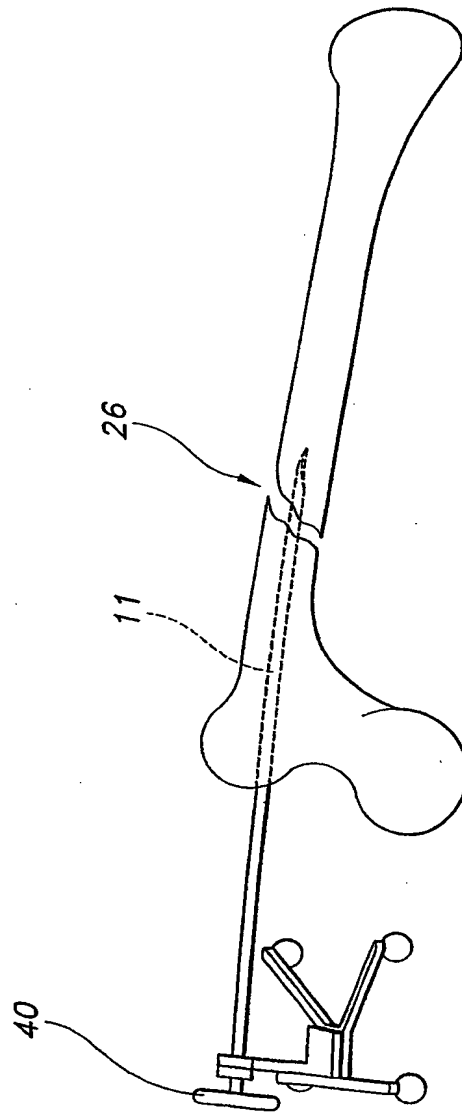


FIG. 13

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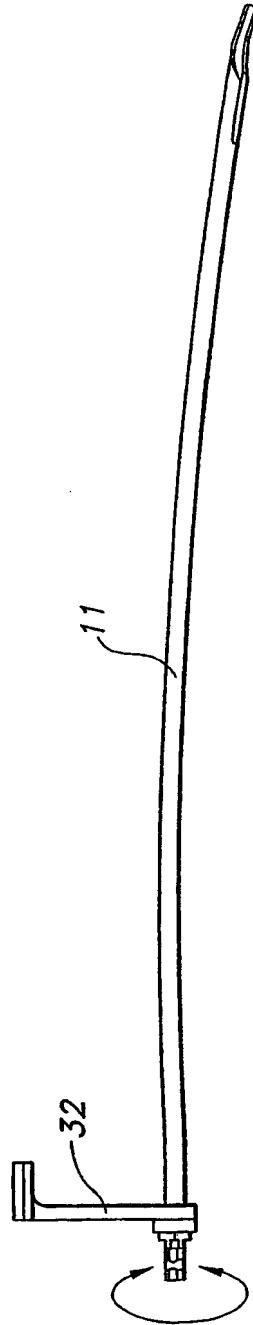


FIG. 14

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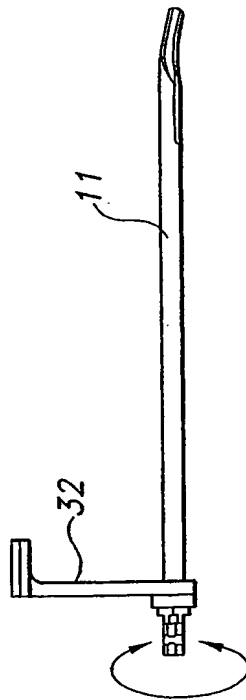


FIG. 15

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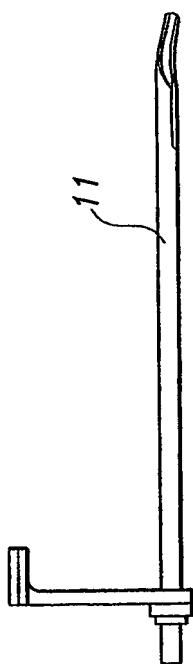
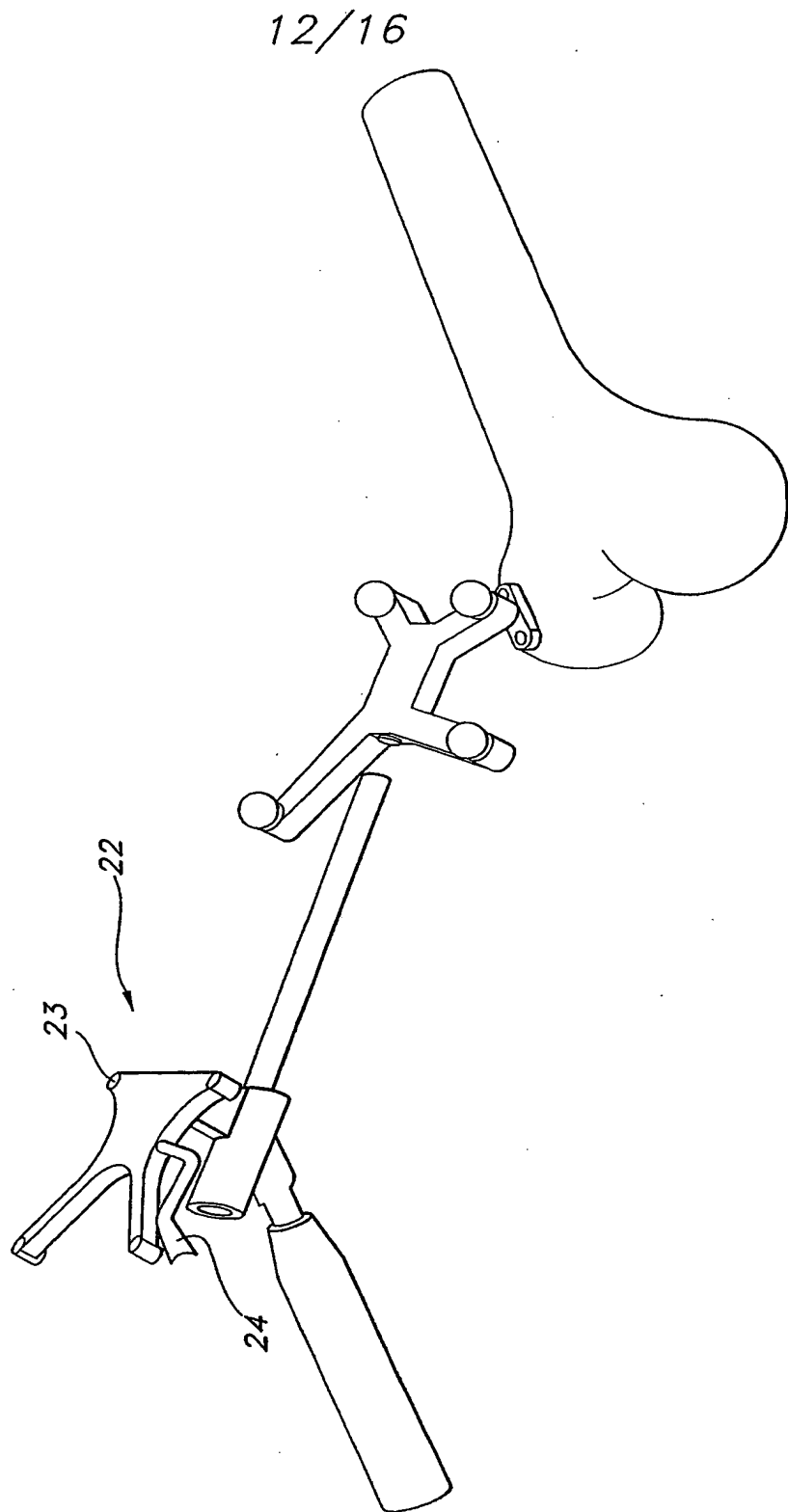


FIG. 16



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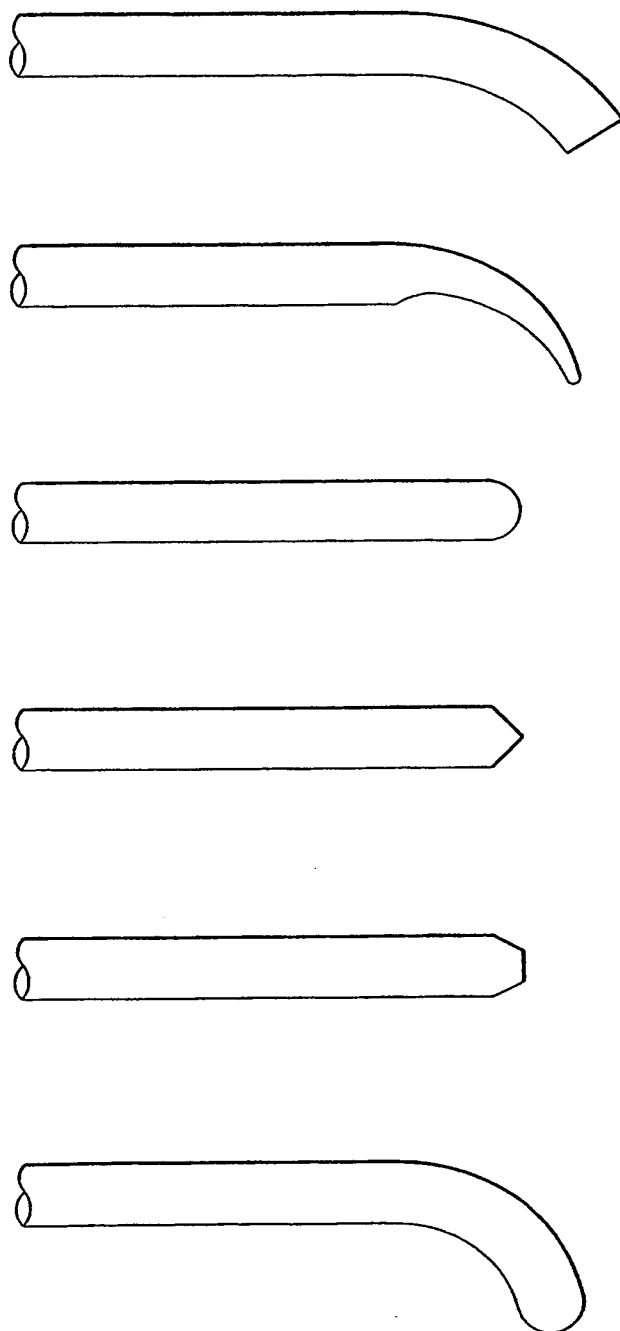


FIG. 18

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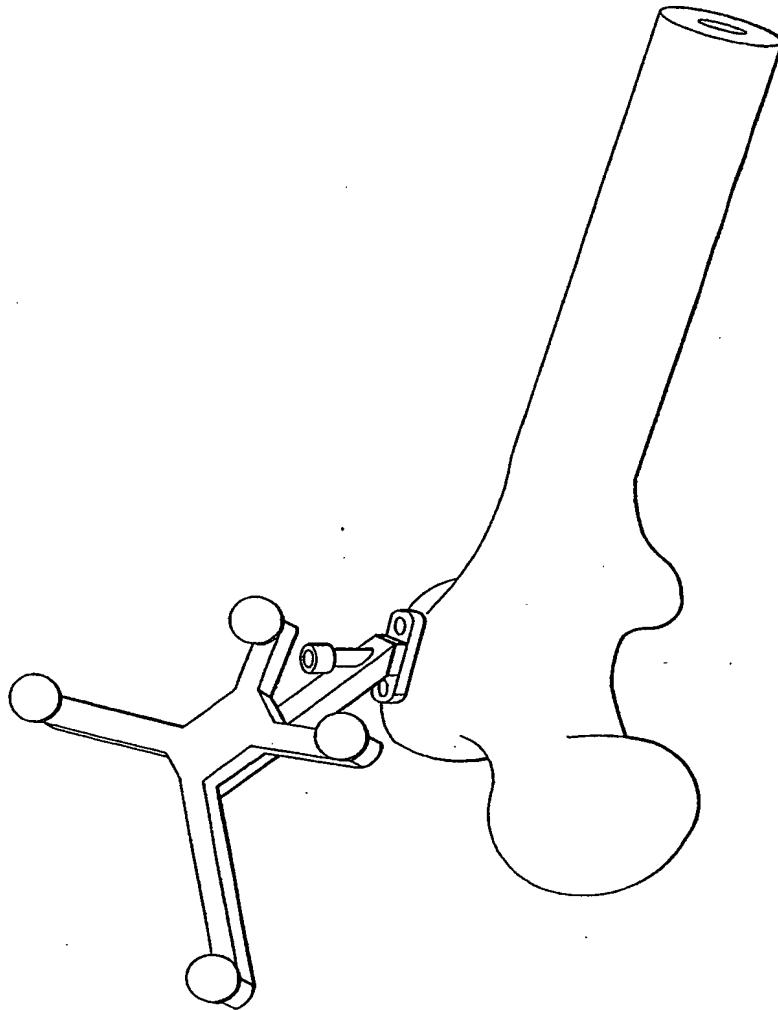


FIG. 19

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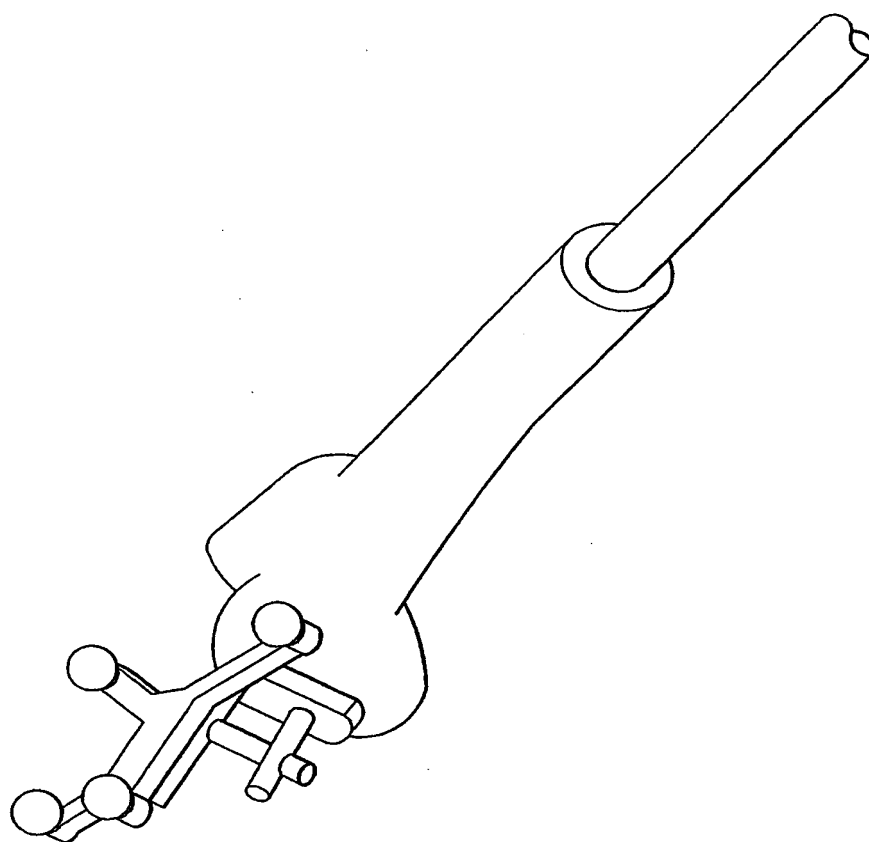


FIG. 20

16/16

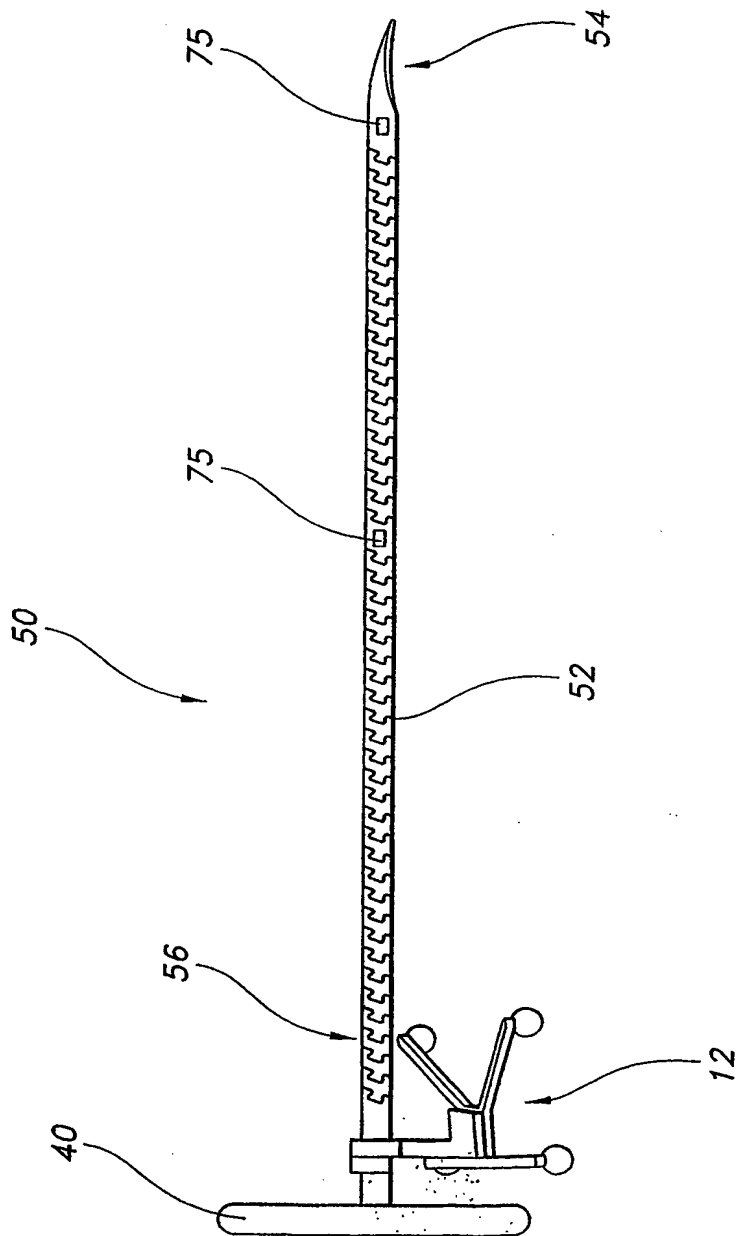


FIG. 21

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/04268

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/72 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 47103 A (SURGICAL INSIGHTS INC) 17 August 2000 (2000-08-17)	1,2,4,5, 10,11
Y	page 54, line 2 -page 58, line 14; figure 18	3,6-9,12
X	PATENT ABSTRACTS OF JAPAN vol. 2002, no. 05, 3 May 2002 (2002-05-03) & JP 2002 017740 A (OCHI TAKAHIRO;YONENOBU SAKUO; MMT:KK), 22 January 2002 (2002-01-22) abstract	1,12,15
Y	US 6 190 395 B1 (WILLIAMS THOMAS R) 20 February 2001 (2001-02-20) column 4, line 66 -column 6, line 9	3,6-9
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

6 June 2003

Date of mailing of the international search report

25/06/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax (+31-70) 340-3016

Authorized officer

Angeli, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/04268

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 879 352 A (FILOSO SILVANO ET AL) 9 March 1999 (1999-03-09) column 2, line 1-16	12
A	WO 98 29032 A (BEN HAIM SHLOMO ;BIOSENSE INC (US)) 9 July 1998 (1998-07-09) page 7, line 1-14 page 8, line 27 - line 35	13, 14

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/04268

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-39
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for diagnosis and for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 03/04268

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0047103	A	17-08-2000	US 6285902 B1	04-09-2001
			AU 3857900 A	29-08-2000
			EP 1158891 A2	05-12-2001
			WO 0047103 A2	17-08-2000
			US 2001036245 A1	01-11-2001
JP 2002017740	A	22-01-2002	NONE	
US 6190395	B1	20-02-2001	NONE	
US 5879352	A	09-03-1999	CA 2160507 A1	15-04-1996
			DE 69510516 D1	05-08-1999
			DE 69510516 T2	18-11-1999
			EP 0706782 A2	17-04-1996
			ES 2135635 T3	01-11-1999
			JP 8206130 A	13-08-1996
WO 9829032	A	09-07-1998	AU 1616897 A	02-09-1997
			AU 728802 B2	18-01-2001
			AU 2711597 A	09-12-1997
			AU 729206 B2	25-01-2001
			AU 3632897 A	20-02-1998
			AU 735196 B2	05-07-2001
			AU 5338798 A	31-07-1998
			AU 741737 B2	06-12-2001
			AU 5338898 A	31-07-1998
			CA 2247942 A1	09-07-1998
			CA 2247992 A1	09-07-1998
			CA 2255807 A1	27-11-1997
			EP 0904127 A1	31-03-1999
			EP 0930917 A1	28-07-1999
			EP 0893967 A1	03-02-1999
			EP 0901341 A1	17-03-1999
			WO 9729682 A1	21-08-1997
			WO 9744089 A1	27-11-1997
			WO 9804321 A1	05-02-1998
			WO 9829032 A1	09-07-1998
			WO 9829033 A1	09-07-1998
			JP 2002511774 T	16-04-2002
			JP 2000508223 T	04-07-2000
			JP 2000508224 T	04-07-2000
			JP 2000514320 T	31-10-2000
			US 6063022 A	16-05-2000
			US 6272371 B1	07-08-2001
			US 6083170 A	04-07-2000
			US 2002183809 A1	05-12-2002
			US 6443974 B1	03-09-2002
			US 6395016 B1	28-05-2002

Form PCT/ISA/210 (patent family annex) (July 1992)

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